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Registration Decision RD2014-10

Novaluron

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Registration Decision for Novaluron

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Technical Insecticide (Novaluron) and its end-use products, Mosquiron 0.12CRD, Mosquiron 0.12CRD-D, Mosquiron 0.12P, and Mosquiron 0.12P-D, containing the technical grade active ingredient novaluron, to control mosquito larvae (excluding *Mansonia* spp. and *Coquilletidia* spp.).

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-19, *Novaluron*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for PRD2013-19 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-19. This decision is consistent with the proposed registration decision stated in PRD2013-19.

For more details on the information presented in this Registration Decision, please refer to PRD2013-19 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticide and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Is Novaluron?

Novaluron is an insect growth regulator for control of mosquito larvae (excluding *Mansonia* spp. and *Coquilletidia* spp.) in standing bodies of water. It inhibits chitin synthesis, affecting moulting of larvae, but does not affect the adult stage after development is completed. Novaluron is also registered to control various pests in many agricultural crops.

Health Considerations

Can Approved Uses of Novaluron Affect Human Health?

Mosquiron 0.12CRD, Mosquiron 0.12CRD-D, Mosquiron 0.12P, and Mosquiron 0.12P-D, containing novaluron, are unlikely to affect your health when used according to label directions.

Potential exposure to novaluron may occur when handling and applying the end-use products. When assessing health risks, two key factors are considered: the levels where no health effects occur, and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only those uses where exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when using pesticide products according to label directions.

In laboratory animals, novaluron technical grade active ingredient and Mosquiron 0.12CRD, Mosquiron 0.12CRD-D, Mosquiron 0.12P, and Mosquiron 0.12P-D were of low acute oral and dermal toxicity, minimally irritating to the eyes and did not cause an allergic skin reaction. Novaluron was non-irritating to the skin while the Mosquiron end-use products were minimally irritating to the skin. Novaluron was of low acute toxicity via the inhalation route; due to the use pattern and the formulation of the end-use products, exposure via the inhalation route is not expected.

Novaluron did not cause cancer in animals and did not damage genetic material. There was no indication that novaluron damaged the nervous system. Novaluron did not cause birth defects in animals and there were no effects on the animal's ability to reproduce. Health effects in animals given repeated doses of novaluron included damage to red blood cells.

When novaluron was given to pregnant or nursing animals, effects on the juvenile animal (changes in body weight and body weight gain, and increases in spleen and liver weight) were observed at doses that were toxic to the mother, indicating that the young do not appear to be more sensitive to novaluron than the adult animal.

The risk assessment protects against these effects by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests.

Residues in Water and Food

A risk assessment for residues in water and food was not required for this application as the proposed uses do not include dietary exposure.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for non-occupational exposure is not of concern.

A quantitative risk assessment conducted for homeowners applying Mosquiron 0.12CRD-D and Mosquiron 0.12P-D to standing water indicated that the risk is not of concern.

Occupational Risks From Handling Mosquiron 0.12CRD or Mosquiron 0.12P

Occupational risks are not of concern when Mosquiron 0.12CRD or Mosquiron 0.12P are used according to the proposed label directions, which include protective measures.

A quantitative risk assessment conducted for individuals handling Mosquiron 0.12CRD, or Mosquiron 0.12P products, indicated that the risk for workers is not of concern when these products are used according to label directions.

Workers applying Mosquiron 0.12CRD or Mosquiron 0.12P can come in direct contact with novaluron on the skin or through inhalation. Therefore, the label will specify that workers must wear a long-sleeved shirt, long pants and chemical-resistant gloves when applying Mosquiron 0.12CRD or Mosquiron 0.12P to standing water.

Environmental Considerations

What Happens When Novaluron Is Introduced Into the Environment?

Novaluron is toxic to aquatic invertebrates. Marine and freshwater invertebrates are at risk.

Novaluron is used in the formulation of Mosquiron 0.12CRD, Mosquiron 0.12CRD-D, Mosquiron 0.12P, and Mosquiron 0.12P-D. Once applied to water for mosquito larval control novaluron is expected to be non-persistent to slightly persistent. Novaluron is slightly persistent in sediments but is not expected to be mobile or leach into groundwater or volatilize into air.

Novaluron is very highly toxic to freshwater and marine invertebrates on an acute and chronic basis and shows negligible toxicity to freshwater and marine fish, algae and aquatic vascular plants. Novaluron presents a risk to freshwater and marine aquatic invertebrates. Therefore, hazard statements and label statements placing restrictions on potential use-sites will be required.

Value Considerations

What Is the Value of Mosquiron 0.12CRD, Mosquiron 0.12CRD-D, Mosquiron 0.12P, and Mosquiron 0.12P-D?

Novaluron is an insect growth regulator used in the Mosquiron line of end-use products to control mosquito larvae (excluding *Mansonia* spp. and *Coquilletidia* spp.) in standing bodies of water for up to 90 days.

Mosquiron 0.12CRD and Mosquiron 0.12P are restricted class products that are to be applied by public health officials, mosquito abatement officials and other trained personnel. Mosquiron 0.12CRD-D and Mosquiron P-D are domestic class products. The Mosquiron line of end-use products control mosquito larvae in standing bodies of water at concentrations of 120 to 240 µg novaluron/L of water. The Mosquiron line of end-use products are compatible with current mosquito management practices and have the potential to reduce or replace the use of organophosphates in standing bodies of water. Novaluron may be used in rotation with mosquito larvicides having a different mode of action to aid in resistance management.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Mosquiron 0.12CRD, Mosquiron 0.12CRD-D, Mosquiron 0.12P, and Mosquiron 0.12P-D to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Anyone handling Mosquiron 0.12CRD or Mosquiron 0.12P, in an occupational setting, must wear the personal protective equipment as stated on the label.

Environment

Precautionary measures are required to mitigate potential risks to non-target aquatic invertebrates. These include adding statements to the label regarding environmental hazard and the directions for use.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2013-19) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

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[5] As per subsection 35(1) of the *Pest Control Products Act*.